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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,225	09/16/2003	Pontus von Bahr	514862000700	3377
20872 7590 01/03/2008 MORRISON & FOERSTER LLP 425 MARKET STREET SAN FRANCISCO, CA 94105-2482			EXAMINER ALEXANDER, LYLE	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 01/03/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,225	<b>Applicant(s)</b> VON BAHR ET AL.	
	<b>Examiner</b> Lyle A. Alexander	<b>Art Unit</b> 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16, 18-24, 26, 27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-24, 26-27 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 6-9 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 does not further limit the position of the flow regulator(6). Claim 1 specifies the inlet, NO scrubber, flow regulator, buffer chamber and NO sensor. Claim 2 states the flow regulator is connected to the inlet and buffer chamber which does not further limit claim 1 or further define its relationship with the scrubber.

Claim 6 is not clear what type of "control electronics" is intended to verify the parameters and control exhalation.

Claim 10 uses the terms "long" and "small" which are not clear (e.g. "... a **long** channel having a **small** cross-section"). These relative terms should be deleted.

Claims 26 states, in the preamble, the patient is entering information into a user interface. The second step "... the patient subjectively assesses ... enters corresponding information" fails to state the data is entered into the user interface. If Applicants' were to add this language the 35 USC 112 second paragraph rejection of this claim would be vacated.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-13,18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0904729 (referenced hereafter as EP) in view of Birks et al. (USP 7,045,359).

Figure 1 show the ventilator(2) connected to a patient(4). The expired gas is transferred via line(8) to the analysis unit(10). The gas is supplied to a mixing chamber(20) before sample measurement. Subsequently, the gas is carried through a first check valve(24) to a first reciprocating pump(30) where the gas is pressurized and when the desired pressure is obtained the gas goes past the second check valve(34) to a second reciprocating pump(36) that compresses the gas to a much smaller volume (e.g. a third or tenth as large) and has been read on the claimed *buffer chamber*. Regulator switch(40) controls the first and second gas lines. The combination of the check valves and switch has been read on the pressure regulators and pressure sensor respectively. Paragraph [0029] teaches use of a dehumidifier(44) which has been read on the claimed means to equalize the humidity. Paragraph[0031] teaches the analysis unit(52) is a traditional spectrophotometer and has been read on the claimed *NO sensor*. The gas lines taught after the pumps have been read on the claimed *buffer chamber consist of a length of tube*. Additionally, the claimed limitations specifying the flow of the gas and/or feedback to the patient, the Office maintains EP has the appropriate means to accomplish all of these functions.

EP is silent to the claimed maze shape of the chamber, the specific type of audible feedback given to the patient and the claimed flow rates.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. Selection of audible feedback

and the chosen rates of flow have well known and expected results and would be result effective variables.

It would have been within the skill of the art to modify EP and use audible feedback, a flow rate of 0.5-10 ml/s to the sensor and the flow rate up to the sensor lower than the exhalation flow rate as optimization of result effective variables.

EP is silent to the use of NO scrubber.

Birks et al. use a NO scrubber on a sample prior to the analyzer to aide in the NO calculations and calibrations.

It would have been within the skill of the art to modify EP in view of Birks et al. and use a NO scrubber on the breath sample prior to analysis to gain the above advantages.

Claims 14-15, 26-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0904729 (referenced hereafter as EP) in view of Birks et al. as applied to claims 1-13, 18-23 above, and further in view of Holowko et al.

See EP supra.

EP is silent to the use of the claimed "smartcard".

Holowko et al. a smartcard is desirable because it will store all of the patient's pertinent medical information and history. This is advantageous because many patients may not accurately remember their medical history or may be impaired and unable to communicate. Holowko et al. further teach current information can be continually added to the smartcard.

It would have been within the skill of the art to modify EP in view of Holowko et al. and use a smartcard to contain specific patient information to gain the above advantages.

Claims 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0904729 (referenced hereafter as EP) in view of Birks et al. as applied to claims 11-13, 18-23 above, and further in view of Oswin et al.

See EP supra.

EP teaches use of a convention spectrophotometry to determine the NO and is silent to the claimed electrochemical cell.

Oswin et al. teach measurements of breath oxides using an electrochemical cell. The abstract teaches electrochemical cells are advantageous because they do not require additional heat input.

It would have been within the skill of the art to modify EP in view of Oswin et al. and use an electrochemical cell to gain the above advantages.

### ***Response to Arguments***

Applicant's arguments filed 10/18/07 have been fully considered but they are not persuasive.

Applicant's state EP 0904729 fails to teach controlling the flow rate of the sample. The pending apparatus claims contain the new limitations "... wherein said suitable flow rate for the sensor is lower than the exhalation flow rate " which does not specify any structural limitations and appears to be a method of intended use of an apparatus which is of no patentable moment with respect to the pending apparatus

claims. The Office maintains EP 0904729 teaches pressurization of the sample and has been properly read on the flow regulation of the instant claims.

Applicant's traverse the 35 USC 103 rejections over EP 0904729 in view of Oswin et al. stating Oswin teach away from EP 0904729. The Office maintains both references are directed to detection of NO compounds and have been properly combined.

Applicants traverse the application of Birks et al. stating this reference is directed to measuring a different analyte (e.g. ozone) and there is no motivation to make the combination. The Office maintains Birks et al. was cited to teach the use of a scrubber and not for the detection of the specific analyte. Further, the Office maintains the rejections of record provide sufficient motivation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

